FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

The Inn and Conference Center, University of Maryland University College (UMUC)
Marriott Conference Centers
3501 University Blvd. East, Adelphi, MD

OCTOBER 14, 2009

AGENDA

The committee will discuss new drug application (NDA) 22-250, with the newly proposed trade name AMPRIVA (fampridine) 10 milligram (mg) tablets, manufactured by Acorda Therapeutics, Inc. The proposed indication for this new drug product is to improve walking ability in individuals with multiple sclerosis (MS). MS is a neurological disease that may cause a wide variety of possible symptoms, including in some patients difficulty in walking.

8:00 a.m.	Call to Order and Opening Remarks	**Britt Anderson, M.D., Ph.D.** Acting Chair Peripheral and Central Nervous System Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	**Diem-Kieu H. Ngo, Pharm.D., BCPS** Designated Federal Official
8:15 a.m.	FDA Introductory Remarks	**Russell Katz, M.D.** Director, Division of Neurology Products (DNP), Office of Drug Evaluation I (ODE I), Office of New Drugs (OND), CDER, FDA
8:30 a.m.	**INDUSTRY PRESENTATION** *Fampridine-SR for Improved Walking Ability in Patients with Multiple Sclerosis*	
	Background and Introduction	**Ron Cohen, M.D.** President and CEO, Acorda Therapeutics
	Medical Need and Outcome Measures	**Aaron Miller, M.D.** Corinne Goldsmith Dickinson Center for Multiple Sclerosis and Professor of Neurology Mount Sinai School of Medicine, New York, NY
	Clinical Program: Efficacy	**Andrew Blight, Ph.D.** Chief Scientific Officer, Acorda Therapeutics
	Clinical Program: Safety	**Thomas Wessel, M.D., Ph.D.** Chief Medical Officer, Acorda Therapeutics

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AGENDA
-CONTINUED-

INDUSTRY PRESENTATION (CONT.)

	A Clinical Perspective	**Christine Short, M.D.** Division Chief, Physical Medicine and Rehabilitation Assistant Professor, Department of Medicine Dalhousie University, Halifax, Canada
	Benefit-Risk	**Aaron Miller, M.D.** Corinne Goldsmith Dickinson Center for Multiple Sclerosis and Professor of Neurology Mount Sinai School of Medicine, New York, NY
10:00 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	

FDA PRESENTATION

10:30 a.m.	Fampridine Efficacy Issues	**Kachikwu Illoh, M.D., M.P.H.** Medical Officer, DNP, ODE I OND, CDER, FDA
10:50 a.m.	Fampridine and Seizure Risk	**Gerard Boehm, M.D., M.P.H.** Medical Officer, DNP, ODE I OND, CDER, FDA
11:15 a.m.	Clarifying Questions	
11:30 a.m.	**LUNCH**	
12:30 p.m.	Open Public Hearing	
1:30 p.m.	Panel Discussion/Questions	
3:00 p.m.	**BREAK**	
3:15 p.m.	Panel Discussion/Questions	
5:00 p.m.	**ADJOURNMENT**	